



- a. For Department of Defense supported research, research which involves minors cannot be determined to be exempt.
  - b. For projects following EPA regulations, research involving intentional exposure of pregnant women or children to any substance is prohibited and not approved by the IRB.
2. These regulations protect children who are the subjects of research. The IRB must review projects covered by Subpart D and approve only projects that satisfy the conditions of all applicable sections of Subpart D. This is documented via the *IRB Member Form: Research involving Minors (subpart D) Checklist*.
  - a. This includes identification of the applicable categories of risk
    - i. Category 46.404 / 50.51
    - ii. Category 46.405 / 50.52
    - iii. Category 46.406 / 50.53
    - iv. Category 46.407 / 50.54
  - b. IRB will also document how the research will obtain assent and parental permission in accordance with 45 CFR 46.408 and/or 21 CFR 50.55.
3. When a project involves wards of state or any other agency:
  - a. The IRB will determine and document that the research (a) is related to their status as wards, or (b) will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the children involved as subjects are not wards.
  - b. For research which falls under 46.406/50.53 or 46.407/50.54, The IRB will require the appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or *in loco parentis*.
4. According to Wisconsin State Law, minors are persons under the age of eighteen. The general rule is that a person may consent for their own medical care at the age of eighteen. Therefore, the MCW IRB generally defines children as individuals under eighteen years of age.
5. As Wisconsin law does not specifically address consent of children with majority status to research, the MCW IRB will review issues of consent related to enrollment of these children in research on a case-by-case basis.
6. Certain statutes and case law provide minors with "majority" status in some circumstances, giving them the right to consent to their own medical care. Wisconsin Law defines individuals less than 18 years of age to be minors, and children as defined in federal regulations, and Subpart D applies to such individuals unless:
  - a. An emancipated minor
  - b. A minor who is married, widowed or divorced
  - c. A minor who is a parent
  - d. A mature minor (Wisconsin law recognizes that some minors may be sufficiently "mature" to give consent to medical treatment, even though they do not qualify as "emancipated")
  - e. A minor seeking care for drug addiction, sexually transmitted diseases, emotional disorders, or abortion or mental health treatment

For Department of Defense projects only, active-duty service members and reserve component members are considered to be adults even if they are under the age of eighteen.

#### **Parental permission and assent of minors**

1. Whenever Subpart D applies, the IRB must determine that permission will be obtained from each child's parents or guardian, except as provided by the regulations in addition to the child's

determine if assent is required of some or all children to be enrolled in the research project and will document one or more of the following:

- a. The children are not capable of providing assent based on the age, maturity, or psychological state.
- b. The capability of the children is so limited that they cannot be reasonably consulted.
- c. The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
- d. Assent can be waived using the criteria for waiver of the consent process.



